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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/026,069	12/21/2001	Rosann Kaylor	16978	8157

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EXAMINER	
MICHENER, JENNIFER KOLB	
ART UNIT	PAPER NUMBER
1762	

DATE MAILED: 11/20/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/026,069	KAYLOR ET AL.	
	Examiner	Art Unit	
	Jennifer Kolb Michener	1762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 December 2001*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-35* is/are pending in the application.

4a) Of the above claim(s) *19,20,23,33 and 35* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-18,21,22,24-32 and 34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *3/29/02*.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

   I. Claims 1-32 and 34, drawn to a method of coating, classified in class 427, subclass 2.1.

   II. Claims 33 and 35, drawn to a biosensor, classified in class 435, subclass 7.21.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product as claimed can be made by another and materially different process such as stamping.

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

4. Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II, restriction for examination purposes as indicated is proper.

5. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

6. This application contains claims directed to the following patentably distinct species of the claimed invention: pre-treatments with 1) surfactant, 2) corona discharge, 3) protein, and 4) gas.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1 and 18 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the

case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

7. During a telephone conversation with Rick Shane in October 2003 a provisional election was made with traverse to prosecute the invention of Group I, species 3) claims 1-18, 21-22, 24-32, and 34. Affirmation of this election must be made by applicant in replying to this Office action. Claims 19, 20, and 23 from species 1), 2), and 4) and claims 33 and 35, from Group II, are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 1-18, 21-22, 24-32, and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Everhart et al. (6,060,256) in view of Kasunich ("Gravure: Process and Technology").

Everhart teaches a method of making a diffraction-based diagnostic biosensor film by providing a receptor in fluid and printing the receptor solution onto a substrate (col. 13, line 27 and throughout). The printer is engraved with a pattern of cells (example 6 and throughout), which inherently have a width, height, and depth for acceptance of the receptor solution. After printing, the substrate is dried, forming an exemplary pattern of 10 micron circles or spacing in the micron or submicron lateral range (example 6; col. 1, line 11), overlapping the ranges claimed by Applicant in claims 1, 26-28.

Overlapping ranges are *prima facie* evidence of obviousness. It would have been obvious to one having ordinary skill in the art to have selected the portion of Everhart's

range that corresponds to the claimed range. *In re Malagari*, 184 USPQ 549 (CCPA 1974).

Everhart teaches that the micro-contact printing method comprises application of a receptor solution using ink jet or other imprinting methods (col. 7, line 27) suitable for continuous printing (col. 3, line 2). Everhart also teaches that gravure printing is known in the art for large-scale continuous printing processes (col. 1, line 58). Therefore, while Everhart's micro-contact printing examples are largely directed to stamping, he teaches that other imprinting methods suitable for continuous printing are useful in the method of his invention. Gravure printing is one such printing method. Therefore it would have been obvious to one of ordinary skill in the art to select gravure printing as a suitable micro-contact printing method for the continuous printing method of Everhart.
Everhart does not teach the specifics of gravure printing and therefore Examiner cites Kasunich to teach that gravure printing involves transferring ink solution from a rotating engraved printing cylinder, as required by Applicant (page 3).
Since Everhart teaches gravure printing and Kasunich teaches that gravure printing involves coating with an engraved cylinder, it would have been obvious to one of ordinary skill in the art to use an engraved cylinder to gravure print in the method of Everhart to meet the limitations of such a printing technique.

The receptor of Everhart may be a protein or antibody or nucleic acid, as required by claims 2-4, provided in aqueous and/or phosphate-buffer solutions, as required by claims 5-7 (col. 6; example 6).

Regarding claims 8-9, Everhart fails to teach the viscosity of the receptor solution, however, it is Examiner's position that selection of such a cause effective variable would have been within the skill of an ordinary artisan to optimize how the solution adheres to the cylinder, flows from the cylinder, and adheres to the substrate. Kasunich also (page 237) teaches the need to optimize viscosity when gravure printing.
It is well settled that determination of optimum values of cause effective variables such as these process parameters is within the skill of one practicing in the art. *In re Boesch*, 205 USPQ 215 (CCPA 1980).

Regarding claim 10, the exemplary content of receptor in Example 6 is 0.5 mg/ml, lying within the range of "at least 0.1 mg/ml" claimed by Applicant.

Regarding claims 11 and 12, Kasunich (page 410) teaches the use of alcohol to adjust the viscosity of the receptor solution and it is well-known in the art of gravure printing to use glycerol as a flow agent to adjust viscosity. It would have been obvious to select glycerol as the alcohol taught by Kasunich to maintain good printing viscosity of the receptor solution with the expectation of successful results.

Regarding claim 13, it is Examiner's position that not all of the receptor solution would be transferred to the substrate.

Regarding claims 14-17, Everhart teaches a thermoplastic substrate with a gold metal coating to which the receptor solution is applied (Figure 3; example 6; throughout).

Regarding claims 18 and 21-22, Everhart teaches pre-treatment of the substrate with casein protein (Ex. 6).

After coating, the printed substrate is rinsed and dried (ex 6).

Regarding clams 29-32, it is Examiner's position that it would have been obvious to one of ordinary skill in the art to have the contact angle of the receptor solution with respect to the substrate to be less than the contact angle of the receptor solution with respect to the surface of the gravure cylinder so that the receptor solution has a preference for the substrate over the printing cylinder. Printing would be less effective if the solution preferentially remained on the cylinder. Regarding the specific contact angles, it is Examiner's position that selection of the contact angle would be based on the desired viscosity (outlined above) and cohesion suitable for efficient printing. Solutions that are too thick or too thin have negative impacts, as outlined by Kasunich.

It is well settled that determination of optimum values of cause effective variables such as these process parameters is within the skill of one practicing in the art. *In re Boesch*, 205 USPQ 215 (CCPA 1980).

The limitations of claim 34 have been addressed above in light of the rejection of claim 1.

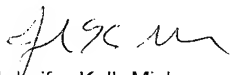
Conclusion

12. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kolb Michener whose telephone number through December 10, 2003 is 703-306-5462 (after 12/10/03: 571-272-1424). The examiner can normally be reached on Monday through Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shrive P. Beck can be reached on 703-308-2333. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9310.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.



Jennifer Kolb Michener
Patent Examiner
Technology Center 1700
November 17, 2003